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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,199	12/20/2001	Byoung S. Kwon	740.013US3	2369

7590 08/25/2004

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EXAMINER	
LANDSMAN, ROBERT S	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/027,199	KWON, BYOUNG S.	
	Examiner	Art Unit	
	Robert Landsman	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 19-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *2, 4, 22 and 23* is/are allowed.

6)☒ Claim(s) *1, 3 and 19-21* is/are rejected.

7)☒ Claim(s) *23* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/21/01*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Sequence Comparisons A and B*.

DETAILED ACTION

1. Formal Matters

A. The Preliminary Amendment dated 12/20/01 has been entered into the record.

B. The Information Disclosure Statement dated 12/20/01 has been entered into the record.

C. Based on the Preliminary Amendment dated 12/20/01, claims 1-23 were pending and were subject to restriction in the Office Action dated 6/28/04. In the Response dated 7/27/04, Applicants elected Group I, claims 1-4 and argued that claims 19-23 should be included in the elected Group. Claim 19 includes SEQ ID NO:3-8. Therefore, this argument is persuasive in part. Claims 19-23 will be combined with the elected Group. However, claims 19-23 will only be examined insofar as they read on SEQ ID NO:1 and 2.

Regarding claims 19, SEQ ID NO:3-8 are independent and distinct, each from each other, because they are products which possess characteristic differences in structure and function and each has an independent utility that is distinct for each invention which cannot be exchanged.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter as defined by MPEP § 808.02, the Examiner has *prima facie* shown a serious burden of search (see MPEP § 803). Therefore, an initial requirement of restriction for examination purposes as indicated is proper.

Applicants may traverse. However, it is believed, since SEQ ID NO:1 and 2 are the predominant SEQ ID NOs in claims 1-4 and 19-23, that Applicants will elect SEQ ID NO:1 and 2. Therefore, to maintain compact prosecution, this Office Action relates to SEQ ID NO:1 and 2 only.

2. Specification

A. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Nucleic acid molecules encoding human H4-1BB.

3. Claim Objections

A. The syntax of claim 23 can be improved by amending the phrase "which is no SEQ ID NO:2 or the extracellular domain thereof" to "which is neither SEQ ID NO:2, nor the extracellular domain thereof."

3. Claim Rejections - 35 USC § 112,first paragraph - enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

A. Claim 3 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The deposit of the biological material is considered necessary for the enablement of the current invention (see MPEP Chapter 2400 and 37 C.F.R. §§ 1.801-1.809). Elements required for practicing a claimed invention must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If a deposit (NRRL B21131) is made under the terms of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (e.g. see 961 OG 21, 1977), and Applicants, their assignee or their agent needs to provide a declaration containing the following:

1. the current address of the ATCC.
2. a declaration, or statement over attorney's signature stating that all restrictions imposed by the depositor on the availability to the public of the deposited biological material be irrevocably removed upon the granting of the patent (see MPEP Chapter 2410.01 and 37 C.F.R. § 1.808.

B. Claims 20 and 21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polynucleotides of SEQ ID NO:1 encoding the H4-1BB receptor of SEQ ID NO:2, does not reasonably provide enablement for fragments of less than the full length of SEQ ID NO:1 which encode H4-1BB receptors. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

In In re Wands, 8USPQ2d, 1400 (CAFC 1988) page 1404, the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of

experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The breadth of the claims is excessive with regard to Applicants' claiming nucleic acids encoding H4-1BB which are less than the full-length of SEQ ID NO:1. Claim 21 encompasses any H4-1BB receptor comprising bases 41-598 and 41-805 of SEQ ID NO:1. However, Applicants provide no guidance or working examples of any protein encoded by any nucleic acid molecule less than that of SEQ ID NO:1. Nucleic acid molecules which comprise less than the full-length of SEQ ID NO:1 would have one or more nucleic acid substitutions, deletions, insertions and/or additions to the polynucleotide of SEQ ID NO:1. Applicants have not taught which bases are critical to maintain the functional characteristics of the H4-1BB protein, nor would it be predictable to the artisan which bases would be required to maintain this function.

Therefore, in summary, the breadth of the claims is excessive with regard to nucleic acids encoding H4-1BB which are less than the full-length of SEQ ID NO:1. There is no guidance or working examples of any protein encoded by any nucleic acid molecule less than that of SEQ ID NO:1, nor would it be predictable to the artisan which bases would be required to maintain receptor function. For these reasons, the Examiner holds that undue experimentation would be required to practice the claimed invention.

4. Claim Rejections - 35 USC § 112,first paragraph – written description

A. Claims 20 and 21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These are genus claims. Nucleic acid molecules which comprise bases 41-598 or 41-805 of SEQ ID NO:1 would have one or more nucleic acid substitutions, deletions, insertions and/or additions to said polynucleotide.The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. The specification and claims do not provide any guidance as to what changes should be made. Structural features that could distinguish compounds in the genus from others in the nucleic acid or protein class are missing

from the disclosure. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, SEQ ID NO:1 alone are insufficient to describe the genus. One of skill in the art would reasonable conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus at the time the invention was made.

5. Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

A. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites that the Deposit is an NRRL Deposit. However, page 4, lines 25-28 states that the Deposit is an ATCC Deposit.

6. Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

A. Claims 1 and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Goodwin et al. (US Patent 5,674,704 -see IDS of 10/21/01). The claims recite a nucleic acid encoding SEQ ID NO:2, or the extracellular domain thereof. Goodwin teach a nucleic acid encoding a protein which is 100% identical to SEQ ID NO:2 (Sequence Comparisons A and B).

7. Conclusion

A. Claims 2, 4, 22 and 23 are allowable.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (571) 272-0888. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961.

Official papers filed by fax should be directed to (703) 872-9306. Fax draft or informal communications with the examiner should be directed to (571) 273-0888.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-0700.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
August 23, 2004

ROBERT LANDSMAN
PATENT EXAMINER

Sequence Comparison A

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; Sequence 8, Application US/08236918A
; Patent No. 5674704
;  GENERAL INFORMATION:
;    APPLICANT:  Alderson, Mark R.
;    APPLICANT:  Goodwin, Raymond G.
;    APPLICANT:  Smith, Craig A.
;    TITLE OF INVENTION:  Cytokine Designated 4-1BB Ligand
;    NUMBER OF SEQUENCES:  18
;    CORRESPONDENCE ADDRESS:
;      ADDRESSEE:  Kathryn A. Anderson, Immunex Corporation
;      STREET:  51 University Street
;      CITY:  Seattle
;      STATE:  Washington
;      COUNTRY:  US
;      ZIP:  98101
;    COMPUTER READABLE FORM:
;      MEDIUM TYPE:  Floppy disk
;      COMPUTER:  Apple Power Macintosh
;      OPERATING SYSTEM:  Apple 7.5.3
;      SOFTWARE:  Microsoft Word, Version #6.0.1
;    CURRENT APPLICATION DATA:
;      APPLICATION NUMBER:  US/08/236,918A
;      FILING DATE:  06-May-1994
;      CLASSIFICATION:  435
;    PRIOR APPLICATION DATA:
;      APPLICATION NUMBER:  US 08/060,843
;      FILING DATE:  07-May-1993
;      CLASSIFICATION:  435
;    ATTORNEY/AGENT INFORMATION:
;      NAME:  Anderson, Kathryn A.
;      REGISTRATION NUMBER:  32,172
;      REFERENCE/DOCKET NUMBER:  2801-B
;    TELECOMMUNICATION INFORMATION:
;      TELEPHONE:  (206) 587-0430
;      TELEFAX:  (206) 233-0644
;  INFORMATION FOR SEQ ID NO:  8:
;    MOLECULE TYPE:  protein
US-08-236-918A-8

  Query Match             100.0%;  Score 1415;  DB 1;  Length 255;
  Best Local Similarity   100.0%;  Pred. No. 5.5e-120;
  Matches  255;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy          1 MGNSCYNIVATLLLVLNFERTRSLQDPCSNCPAGTFCDNNRNQICSPCPPNSFSSAGGQR 60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          1 MGNSCYNIVATLLLVLNFERTRSLQDPCSNCPAGTFCDNNRNQICSPCPPNSFSSAGGQR 60

Qy         61 TCDICRQCKGVFRTRKECSSTSNAECDCTPGFHCLGAGCSMCEQDCKQGQELTKKGCKDC 120
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         61 TCDICRQCKGVFRTRKECSSTSNAECDCTPGFHCLGAGCSMCEQDCKQGQELTKKGCKDC 120

Qy        121 CFGTFNDQKRGICRPWTNCSLDGKSVLVNGTKERDVVCGPSPADLSPGASSVTPPAPARE 180
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        121 CFGTFNDQKRGICRPWTNCSLDGKSVLVNGTKERDVVCGPSPADLSPGASSVTPPAPARE 180

Qy        181 PGHSPQIISFFLALTSTALLFLLFFLTLRFSVVKRGRKKLLYIFKQPFMRPVQTTQEEDG 240
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        181 PGHSPQIISFFLALTSTALLFLLFFLTLRFSVVKRGRKKLLYIFKQPFMRPVQTTQEEDG 240

Qy        241 CSCRFPEEEEGGCEL 255
              |||||||||||||||
Db        241 CSCRFPEEEEGGCEL 255
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Sequence Comparison B

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LOCUS       I68025                 1415 bp    DNA     linear   PAT 04-FEB-1998
DEFINITION  Sequence 7 from patent US 5674704.
ACCESSION   I68025
VERSION     I68025.1  GI:2830147
KEYWORDS    .
SOURCE      Unknown.
  ORGANISM  Unknown.
            Unclassified.
REFERENCE   1  (bases 1 to 1415)
  AUTHORS   Goodwin,R.G., Smith,C.A. and Alderson,M.R.
  TITLE     Cytokine designated 4-IBB ligand
  JOURNAL   Patent: US 5674704-A 7 07-OCT-1997;
FEATURES             Location/Qualifiers
     source          1. .1415
                     /organism="unknown"
                     /mol_type="unassigned DNA"
ORIGIN

Alignment Scores:
Pred. No.:              1.03e-95        Length:         1415
Score:                  1415.00         Matches:        255
Percent Similarity:     100.00%         Conservative:   0
Best Local Similarity:  100.00%         Mismatches:     0
Query Match:            100.00%         Indels:         0
DB:                     6               Gaps:           0

US-10-027-199-2 (1-255) x I68025 (1-1415)

Qy          1 MetGlyAsnSerCysTyrAsnIleValAlaThrLeuLeuLeuValLeuAsnPheGluArg 20
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        120 ATGGGAAACAGCTGTTACAACATAGTAGCCACTCTGTTGCTGGTCCTCAACTTTGAGAGG 179

Qy         21 ThrArgSerLeuGlnAspProCysSerAsnCysProAlaGlyThrPheCysAspAsnAsn 40
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        180 ACAAGATCATTGCAGGATCCTTGTAGTAACTGCCCAGCTGGTACATTCTGTGATAATAAC 239

Qy         41 ArgAsnGlnIleCysSerProCysProProAsnSerPheSerSerAlaGlyGlyGlnArg 60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        240 AGGAATCAGATTTGCAGTCCCTGTCCTCCAAATAGTTTCTCCAGCGCAGGTGGACAAAGG 299

Qy         61 ThrCysAspIleCysArgGlnCysLysGlyValPheArgThrArgLysGluCysSerSer 80
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        300 ACCTGTGACATATGCAGGCAGTGTAAAGGTGTTTTCAGGACCAGGAAGGAGTGTTCCTCC 359

Qy         81 ThrSerAsnAlaGluCysAspCysThrProGlyPheHisCysLeuGlyAlaGlyCysSer 100
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        360 ACCAGCAATGCAGAGTGTGACTGCACTCCAGGGTTTCACTGCCTGGGGGCAGGATGCAGC 419

Qy        101 MetCysGluGlnAspCysLysGlnGlyGlnGluLeuThrLysLysGlyCysLysAspCys 120
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        420 ATGTGTGAACAGGATTGTAAACAAGGTCAAGAACTGACAAAAAAAGGTTGTAAAGACTGT 479

Qy        121 CysPheGlyThrPheAsnAspGlnLysArgGlyIleCysArgProTrpThrAsnCysSer 140
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        480 TGCTTTGGGACATTTAACGATCAGAAACGTGGCATCTGTCGACCCTGGACAAACTGTTCT 539

Qy        141 LeuAspGlyLysSerValLeuValAsnGlyThrLysGluArgAspValValCysGlyPro 160
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        540 TTGGATGGAAAGTCTGTGCTTGTGAATGGGACGAAGGAGAGGGACGTGGTCTGTGGACCA 599

Qy        161 SerProAlaAspLeuSerProGlyAlaSerSerValThrProProAlaProAlaArgGlu 180
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        600 TCTCCAGCCGACCTCTCTCCGGGAGCATCCTCTGTGACCCCGCCTGCCCCTGCGAGAGAG 659
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B

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Qy        181 ProGlyHisSerProGlnIleIleSerPhePheLeuAlaLeuThrSerThrAlaLeuLeu 200
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        660 CCAGGACACTCTCCGCAGATCATCTCCTTCTTTCTTGCGCTGACGTCGACTGCGTTGCTC 719

Qy        201 PheLeuLeuPhePheLeuThrLeuArgPheSerValValLysArgGlyArgLysLysLeu 220
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        720 TTCCTGCTGTTCTTCCTCACGCTCCGTTTCTCTGTTGTTAAACGGGGCAGAAAGAAACTC 779

Qy        221 LeuTyrIlePheLysGlnProPheMetArgProValGlnThrThrGlnGluGluAspGly 240
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        780 CTGTATATATTCAAACAACCATTTATGAGACCAGTACAAACTACTCAAGAGGAAGATGGC 839

Qy        241 CysSerCysArgPheProGluGluGluGluGlyGlyCysGluLeu 255
              |||||||||||||||||||||||||||||||||||||||||||||
Db        840 TGTAGCTGCCGATTTCCAGAAGAAGAAGAAGGAGGATGTGAACTG 884
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